

CLAIMS

What is claimed is:

- 5
1. A device for processing a fluid sample, the device comprising a unitary body having formed therein:
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- Sub A1
- a) a reaction chamber for chemically reacting the sample;
- b) a separation region for separating components of the sample; and
- c) a transition region connecting the reaction chamber to the separation region; wherein the reaction chamber, transition region, and separation region are formed in
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- and enclosed by the unitary body, the transition region includes at least one flow restrictor for controlling the flow of fluid between the reaction chamber and the separation region, and the portion of the unitary body defining the transition region has lower thermal conduction than the portion of the body defining the reaction chamber so that the transition region substantially
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- thermally isolates the reaction chamber from the separation region.
2. The device of claim 1, further comprising at least two electrodes coupled to the unitary body, wherein the electrodes are positioned to force the sample to flow from the reaction chamber or transition region into the separation region when a voltage
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- is applied between the electrodes.
3. The device of claim 2, wherein the unitary body comprises a molded polymeric part having the electrodes embedded therein.
4. The device of claim 3, wherein each of the electrodes is embedded in the body such that one end of the electrode protrudes through an external surface of the body and such that the other end of the electrode protrudes into an internal region of the body.

5. The device of claim 2, wherein the device is in combination with and designed to be inserted into an external instrument having a heater for heating the reaction chamber and having electrical connections for supplying power to the electrodes.

6. The combination of claim 5, wherein the instrument further includes optics for detecting separated components of the sample or for optically monitoring the reaction chamber.

7. The device of claim 1, further comprising:

- a) an injection electrode embedded in the unitary body adjacent the reaction chamber;
- b) a separation electrode embedded in the unitary body adjacent the separation region;
- c) a common electrode embedded in the unitary body adjacent the transition region; and
- d) a high molecular weight filter positioned in the transition region such that when a voltage is applied between the injection and common electrodes, high molecular weight species in the sample are transported from the reaction chamber to the transition region and collected on the filter, and such that when a subsequent voltage is applied between the common and separation electrodes, the high molecular weight species collected on the filter are electrophoretically transported into the separation region.

8. The device of claim 1, wherein the portion of the unitary body forming the transition region is narrower than the portion of the body forming the reaction chamber.

9. The device of claim 1, wherein the unitary body defines air pockets surrounding the transition region.

10. The device of claim 1, wherein the separation region comprises an electrophoresis capillary containing a separation material.

11. The device of claim 1, wherein the separation region comprises at least one ligand binding site containing members of a binding pair for coupling to complementary binding pairs in the sample.

12. The device of claim 1, wherein the separation region comprises at least one hybridization site having immobilized reagent for hybridizing target analyte in the sample.

13. The device of claim 1, wherein the flow restrictor comprises a constrictor in the transition region having an inner diameter in the range of .01 to 1.0 mm.

14. The device of claim 1, wherein the unitary body further has formed therein at least one side channel communicating with the transition region for adding reagents to the transition region, and wherein the side channel includes at least one flow controller for controlling the flow of fluids through the channel.

15. The device of claim 14, wherein the side channel connects to the transition region upstream of the flow restrictor, and wherein the transition region further includes a collection area for mixing the sample with the reagents.

16. A method for producing a sample-processing device, the method comprising the steps of:

a) molding a one-piece polymeric body having:

i) a reaction chamber for chemically reacting a sample;

ii) a separation region for separating components of the sample; and

iii) a transition region connecting the reaction chamber to the separation region, wherein the polymeric body is molded such that the reaction

chamber, transition region, and separation region are formed in and enclosed by the body and such that the portion of the body defining the transition region has lower thermal conduction than the portion of the body defining the reaction chamber; and

- 5 b) embedding at least two electrodes in the polymeric body such that the electrodes are positioned to force the sample to flow from the reaction chamber or from the transition region into the separation region when a voltage difference is applied to the electrodes.

- 10 17. The method of claim 16, wherein the electrodes are overmolded in the polymeric body by partially inserting the electrodes at selected locations in a mold so that the electrodes become embedded in the body after material is added to the mold.

- 15 18. The method of claim 17, wherein the electrodes are embedded in the polymeric body by screen-printing or depositing.

19. A device for processing a fluid sample, the device comprising:

- 20 a) a body having formed therein:
- i) a reaction chamber for chemically reacting the sample;
 - 25 ii) a separation region for separating components of the sample; and
 - iii) a transition region connecting the reaction chamber to the separation region, wherein the transition region includes at least one flow restrictor for controlling the flow of fluid between the reaction chamber and the separation region, and wherein the portion of the body defining the transition region has lower thermal conduction than the portion of the body defining the reaction chamber so that the transition region substantially thermally isolates the reaction chamber from the separation region;
- b) an injection electrode embedded in the body adjacent the reaction chamber;

- c) a separation electrode embedded in the body adjacent the separation region;
and
d) a common electrode embedded in the body adjacent the transition region such
that when a voltage is applied between the injection and common electrodes,
the components in the sample are transported from the reaction chamber to
the transition region, and such that when a subsequent voltage is applied
between the common and separation electrodes, the sample components are
electrophoretically transported into the separation region.

20. The device of claim 19, further comprising a high molecular weight filter
positioned in the transition region such that when the voltage is applied between the
injection and common electrodes, high molecular weight species in the sample are
transported from the reaction chamber to the transition region and collected on the
filter, and such that when the subsequent voltage is applied between the common
and separation electrodes, the high molecular weight species collected on the filter
are transported into the separation region.

21. The device of claim 19, wherein the body further has formed therein at least one
side channel communicating with the transition region for adding reagents to the
transition region, and wherein the side channel includes at least one flow controller
for controlling the flow of fluids through the channel.

22. The device of claim 21, wherein the side channel connects to the transition region
upstream of the flow restrictor, and wherein the transition region further includes a
collection area for mixing the sample with the reagents.

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